DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2010

Re: Bryan Cervical Disc System
Docket No.: FDA-2009-E-0583

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,156,067, filed by Medtronic Sofamor Danek, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Bryan Cervical Disc System, the medical device claimed by the patent.

The total length of the regulatory review period for Bryan Cervical Disc System is 2,702 days. Of this time, 1,653 days occurred during the testing phase and 1,049 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: December 20, 2001.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 20, 2001.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: June 29, 2006.

   The applicant claims June 28, 2006, as the date the premarket approval application (PMA) for Bryan Cervical Disc System (PMA P060023) was initially submitted. However, FDA records indicate that PMA P060023 was submitted on June 29, 2006.

3. The date the application was approved: May 12, 2009.

   FDA has verified the applicant's claim that PMA P060023 was approved on May 12, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: William R. Richter
Medtronic Spinal and Biologics
2600 Sofamor Danek Drive
Memphis, TN 38132